JUN 1 8 2013

510(k) Summary of Safety and Effectiveness

iU22 Diagnostic Ultrasound System

This summary of safety and effectiveness information is submitted in accordance with 21CFR §807.92

1. **Submitter's name, address, telephone number, contact person.**

Philips Ultrasound, Inc.
22100 Bothell Everett Hwy
Bothell, WA 98021-8431

Contact person: Jessica Stenberg, Regulatory Affairs Specialist
Email: Jessica.Stenberg@philips.com
Tel: (425) 487-7371
Fax: (425) 487-8666

Date prepared: February 20, 2013

2. **Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:**

Common/usual name: Diagnostic ultrasound system and transducers
Proprietary name: iU22 Ultrasound System

These devices are classified as follows:

Classification Name	21 CFR Section	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90IYO
Diagnostic Ultrasound Transducer	892.1570	90ITX

As stated in 21 CFR, parts 892.1550, 892.1560 and 892.1570, each of these generic types of devices have been classified as Class II.

3. **Substantially Equivalent Devices**

Philips Ultrasound believes that the modifications to the iU22 Ultrasound System is substantially equivalent to the following currently marketed devices:

Product	510(k)
Philips iU22	K093563
SuperSonic Aixplorer	K112255

4. Device Description and Technical Comparison to Predicate Devices

The subject of this 510(k) notification, the modifications to the iU22 ultrasound system and transducer(s), function in a manner identical to all diagnostic ultrasound systems and transducers. The system circuitry generates an electronic voltage pulse, which is transmitted to the transducer. In the transducer, a piezo electric array converts the electronic pulse into an ultrasonic pressure wave. When coupled to the body, the pressure wave transmits through body tissues. The Doppler functions of system process the Doppler shift frequencies from the echoes of moving targets such as blood to detect and graphically display the Doppler shifts of these tissues as flow.

ElastPQ is the Philips Ultrasound marketing name for a feature commonly referred to as shear wave elastography. The terms will be used interchangeably throughout the submission and supplemental information.

The ElastPQ (shear wave) feature provides the user with tissue stiffness information. The iU22 Ultrasound system was cleared for Elastography modes per 510(k) K093563. ElastPQ is an Elastography mode on the iU22 Ultrasound Scanner where a burst of Doppler-type "push" pulses with high intensity and long pulse duration is transmitted. This mode creates waves in soft tissues and estimates the tissue stiffness by determining the speed at which these shear waves travel. This shear wave technology is similar to the ShearWave™ feature recently cleared on Aixplorer® by SuperSonic Imagine, Inc, per 510(k) K112255.

The iU22 system gives the operator the ability to measure anatomical structures and offers analysis packages that provide information used by competent healthcare professionals to make a diagnosis.

5. Intended Use

The iU22 Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (or 2-D), M-mode (including Anatomical M-mode), Pulse Wave Doppler, Continuous Wave Doppler, Color Doppler, Tissue Doppler Imaging, Harmonics (Tissue and Contrast) and Elastography modes (including ElastPQ). It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications:

Ophthalmic
Fetal
Intra-operative
Abdominal
Laparoscopic
Pediatric

Small Organ
Adult and Neonatal Cephalic
Trans-rectal
Trans-vaginal
Musculoskeletal
Urology
Cardiac (Adult, Pediatric, Trans-esophageal)
Fetal Echo
Peripheral Vessel

The clinical environments where the iU22 4.3 system can be used include point-of-care areas in offices, clinical and hospital settings for diagnosis of patients.

6. Indications for Use

The 510(k) Indications for Use forms on the following 2 pages show previously cleared indications for use for the iU22 system and the new mode of operation (ElastPQ) added with this 4.3 release of iU22. The iU22 4.3 release adds a new mode of operation (ElastPQ) for the C5-1 transducer so the Indications for Use form for C5-1is also included in this submission. All other previously cleared transducers used for the iU22 remain unchanged.

7. Safety Considerations

As a track 3 ultrasound device the iU22 Ultrasound system is designed to comply with the *Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment* (AIUM/NEMA 2004).

iU22 Ultrasound complies with the referenced standard as well as the FDA ultrasound specific guidance, *Guidance for Industry and FDA Staff – Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers* (September 9, 2008).

The acoustic output limits for Non-Ophthalmic Applications are:

- Ispta.3 ≤ 720 MW/cm^2
- MI ≤ 1.9
- TI ≤ 6.0

The system and transducers are also complaint to:

- IEC 60601-1 Medical Electrical Equipment Part 1, general requirements for safety 1988 Amendment, 1991-11, Amendment 2, 1995
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2, General Requirements for Safety – Collateral Standard Electromagnetic Compatibility, 2000
- IEC 60601-2-37 Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment, 2007

8. Nonclinical Performance Data

Philips Ultrasound performed the following testing to ensure the safety and effectiveness of the modified iU22 device:

- **Shear Wave Elastography Thermal Test** – The purpose of this testing was to understand the thermal implications of shear wave.
- **ElastPQ Measurement Report** – A bench test of the iU22 ultrasound system in ElastPQ mode in order to verify precision and reproducibility.
- **Software Verification and Validation** – Standard verification and validation testing in order to ensure the system meets specifications and user needs.

9. Clinical Data

A clinical trial was not required to demonstrate safety and effectiveness of the ElastPQ Elastography mode. As part of our investigation a review of all relevant field information was performed resulting in the conclusion the technology is safe.

A usability study on ElastPQ was performed following the FDA's draft guidance on human factofs (June 2011). This work was conducted to ensure the ElastPQ analysis package meets the usability needs of the users.

10. Conclusion

iU22 Ultrasound System and transducers with ElastPQ is substantially equivalent in safety and effectiveness to the predicate devices identified above:

- The systems are indicated for the diagnostic ultrasonic imaging and fluid flow analysis.
- The systems have the same gray-scale and Doppler capabilities.
- The systems have acoustic output levels below the Track 3 FDA limits.
- The systems are manufactured under equivalent quality systems.
- The systems are manufactured of materials with equivalent biosafety. The materials have been evaluated and found to be safe for this application.
- The systems are designed and manufactured to the same electrical and physical safety standards.

514 Performance Standards

There are no Sec. 514 performance standards for this device.

Prescription Status

This is a prescription device. The prescription device statement appears in the labeling.

Sterilization Sites

Not applicable. No components supplied sterile.

Track

This is a Track 3 system

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 18, 2013

Philips Ultrasound, Inc.
% Ms. Jessica Stenberg
Regulatory Affairs Specialist
22100 Bothell Everett Highway
BOTHELL WA 98021

Re: K130499
Trade/Device Name: iU22 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: May 10, 2013
Received: May 24, 2013

Dear Ms. Stenberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the iU22 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

C5-1

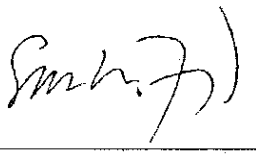
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130499

Device Name: Philips iU22 Diagnostic Ultrasound System

Indications for Use: The iU22 Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (or 2-D), M-mode (including Anatomical M-mode), Pulse Wave Doppler, Continuous Wave Doppler, Color Doppler, Tissue Doppler Imaging, Harmonics (Tissue and Contrast) and Elastography modes (including ElastPQ Liver). It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications:

Ophthalmic
Fetal
Intra-operative
Abdominal
Laparoscopic
Pediatric
Small Organ
Adult and Neonatal Cephalic
Trans-rectal
Trans-vaginal
Musculoskeletal
Urology
Cardiac (Adult, Pediatric, Trans-esophageal)
Fetal Echo
Peripheral Vessel

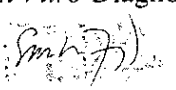
The clinical environments where the iU22 Diagnostic Ultrasound System can be used include Clinical, Hospital, and point-of-care for diagnosis of patients.

These use models are within the scope of and substantially equivalent to current indications for use for the iU22 Diagnostic Ultrasound System.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K130499

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K130499
System: **iU22 Ultrasound System**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic	P	P	P		P	Notes 1,3	Notes, 5,6,8,10,12,13
Fetal Imaging & Other	Fetal (includes Echo)	P	P	P		P	Notes 1,2,3	Notes, 5,6,7,8,10,11,12,13
	Abdominal (includes urology)	P	P	P		P	Notes 1,2,3	Notes, 5,6,7,8,9,10,11,12,13, 16
	Intra-operative (Abdominal, cardiac, spine, Vascular)	P	P	P	P	P	Notes 1,2,3,4	Notes 5,6,8,10,12,13
	Intra-operative (Neuro.)	P	P	P		P	Notes 1, 3	Notes 3,5,6,10,12,13
	Laparoscopic	P	P	P		P	Notes 1, 3	Notes 8,10,12,13
	Pediatric	P	P	P	P	P	Notes 1,2, 3	Notes 5,6,8,9,10,12, 13
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Notes 1,2, 3	Notes 5,6,8,9,10,11,12,13,15
	Neonatal Cephalic	P	P	P		P	Notes 1,3	Notes 5,8,10,12,13
	Adult Cephalic	P	P	P	P	P	Notes 1,3,4	Notes 10, 13
	Trans-rectal	P	P	P		P	Notes 1,3	Notes 5,6,10,11,12, 13
	Trans-vaginal	P	P	P		P	Notes 1,2,3	Notes 5,6,7,10,11,12,13
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Notes 1,2,3	Notes 5,6,8,10,12,13
	Musculo-skel. (Superficial)	P	P	P		P	Notes 1,2,3	Notes 5,6,8,10,12,13
	Intra-luminal							
	Other: Urology	P	P	P		P	Notes 1,3	Notes 5,6,10,12
Cardiac	Cardiac Adult	P	P	P	P	P	Notes 1,2,3,4	Notes 10,11,12,13,14
	Cardiac Pediatric	P	P	P	P	P	Notes 1,2,3,4	Notes 10,11,12,13,14
	Trans-esophageal (Cardiac)	P	P	P	P	P	Notes 1,2,3,4	Notes 10,11,12,13
	Other (Fetal Echo)	P	P	P	P	P	Notes 1,2,3,4	Notes 5,10,12,13
Peripheral Vessel	Peripheral vessel	P	P	P		P	Notes 1,2,3,4	Notes 2,3,5,6,8,9,10,12,13
	Cerebral Vascular	P	P	P		P	Notes 1, 2, 3	Notes 5,6,8,9,10,12,13

N= new indication; P= previously cleared (K093563); E= added under Appendix E (*9/21/2005)
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: EFOV including Amplitude Doppler
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ
Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K130499
System: **iU22 Ultrasound System**
Transducer: **C5-1**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	Notes 1, 3	Notes 5,6,8,10,12,13
	Abdominal	P	P	P		P	Notes 1, 3	Notes 5,6,8,10,12,13, 16
	Intra-operative (cardiac)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Notes 1, 3	Notes 5,6,8,10,12,13
	Small Organ (Breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other *(Specify)*							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Fetal Echo							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Notes 1, 2, 3	Notes 5,6,8,9,10,12,13
	Cerebral Vascular							

N= new indication; P= previously cleared (K093563), E= Added under appendix E.

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: EFOV including Amplitude Doppler
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ
Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging	